Processed Apples Institute

March 4, 2003

Mr. Stuart Shapiro
Desk Officer for the Food and Drug Administration
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, NW
Room 10235
Washington, DC 20503

RE: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Docket No. 02N-0278

Dear Mr. Shapiro:

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the cost estimates outlined in Section IV of the Food and Drug Administration's proposed regulation: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was published in the February 3, 2003, *Federal Register* (68 FR 5428).

Section IV. A. 4.

As stated in Section IV, once the U.S. importer or U.S. purchaser of the food becomes aware of the regulation, he or she would need to find a copy of the prior notice requirements, read the requirements and understand them. The FDA estimates that it takes responsible parties with Internet access one hour to research the prior notice requirements. Table 1 of Section IV shows a first year one-time research cost of $1,865,683 for firms with Internet access. The cost is calculated based on one hour of research time by the administrative worker at a rate of $25.10 and multiplied by 74,330 firms with Internet access.

PAI believes this cost is significantly underestimated and does not take into account the time required to read and understand the prior notice regulation. It may take the administrative worker one-hour to find the document using the Internet, but more time would be required to effectively implement the regulation. The administrative worker would probably not be the person reviewing the document for content or formulating a plan for implementation. This would likely be the responsibility of the firm's manager or in some instances, the company's legal counsel. If we estimate this process takes 10 hours of a manager's time at a rate of $56.74, this would increase the research cost for a firm with Internet access to 567.40 per firm. The research cost of each firm with Internet access would be increased to $592.50 (i.e., 1 hour of time for the administrative worker and 10 hours of time for the manager). Firms that do not have Internet access would incur similar costs, except the time for the administrative worker to research the regulation is two hours instead of one.

02N-0278 C50

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J & K FRESH, LLC

A CUSTOMHOUSE BROKERAGE FIRM

ROSS JONES
LYNNETTE KEFFER

March 4, 2003

Office of Information and Regulatory Affairs
The Office of Management and Budget (OMB)
New Executive Office Building
725 17th Street NW, Room 10235
Washington, DC 20503

Attn: Stuart Shapiro, Desk Officer for FDA

Re: Proposed Bioterrorism Regulations (21 CFR Part 1)

To Whom It May Concern:

This letter contains our comments for the above referenced regulation (as published in the Federal Register, Vol. 68, No. 22, dated February 3, 2003).

J & K Fresh is a Customhouse Brokerage firm specializing in the clearance of imported produce through Customs, FDA, and PPQ/USDA. We clear imported produce from all over the world. I would say our two largest projects are bananas that arrive weekly and the West Coast Chilean Fruit Program. Presently we notify FDA through the OASIS process when we input information in the Customs Automated Broker Interface System. We transmit the shipper's information to FDA. We supply the grower's list when FDA elects to sample. A shipment may have one to one hundred growers. It may also have been packed at more than one packinghouse. (This is especially true with the breakbulk/charter vessels. Some of these shipments have over 1,000,000 pounds of produce.) The Federal Register sites that FDA's OASIS reporting system shows that approximately 2.5 million food entry lines were imported by sea and air transportation in FY 2001. Please note that this figure reflects the transmission of the exporter. Transmitting each grower will, for example on a banana entry, change the one line to well over 100 lines! Realistically, if FDA were going to require each grower/packer to be transmitted a figure of **250 million** FDA lines would be more realistic. The financial implications of taking on an increase of this size are phenomenal. Will FDA have the funds to hire adequate staff to review and release fresh produce in a timely manner?

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Our port (Los Angeles-Long Beach) already has delays with FDA in some areas without this type of additional workload. And it is additional, as we are still required to transmit through OASIS so that we have our line item numbers for the prior notification on the web. The way the proposed law is written will change our *one line banana entry* into **two transmissions of over 200 lines each (a 400% increase)!**

In addition the way the proposed law is written will require importers or their agent to have someone on call 24 hours a day, 7 days a week. Again the additional costs to both the government and private sector will be phenomenal.

If prior notification is not timely or if an error is made, the proposed law states that the product will remain in a "bonded" facility and will be refused entry. This will again require additional personnel to supervise and control this produce. Has a study been done to insure that there are enough bonded facilities available? I foresee the potential for port congestion and disruptions such as we are experiencing presently as an unintended consequence of the 24-hour rule.

One big problem with the system is a lack of communication between the government agencies and the private sector is paying the price! J & K Fresh as well as many of our clients are participants of C-TPAT (Customs-Trade Partnership Against Terrorism). To be a participant, the member must have processes in place that insure the security of the supply chain. There should be a way for FDA to access this information. I think to recognize C-TPAT Certified Members as being secure and low-risk would allow FDA to better target inspections and intercept contaminated products (of importers with no program).

Another tool FDA could utilize is the 24-Hour Rule. Manifest information for ocean vessels is given to Customs 24-hours prior to sailing. It could be mandatory that shipper of food include their FDA Registration number when booking a shipment. It would take far less man-hours for FDA to review the Customs manifest as the prior notification. Within FDA itself, there is the HACCP (Hazard Analysis and Critical Control Points) Program. Again importers participating in this program are low-risk. The main purpose of this law is to insure the food safety. I believe it also can be interactive with the Bioterrorism. Accessing these existing programs could greatly decrease the cost of enacting the Bioterrorism legislation.

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The way this law is written, I would have to double my staff, invest in additional computers (and upgrades), move to a larger office, and change from an 8-hour workday to a 24-hour, 7 day a week work situation. Of course, this would result in a very large rate increase (at least double) which I would have to pass on to my clients. This law (as proposed) will have a devastating effect on our business and our client's. It will trigger price increases of imported produce (like a domino effect) all the way to the consumer level.

I urge FDA to reconsider utilizing some of the programs that are in place, including the OASIS program, which would be more cost effective. The items required in the prior notification process of the proposed law are being transmitted presently (to OASIS) with the exception of the Registration Number of the Exporter. I believe there is a way we can transmit the Registration Number as an Affirmation of Compliance Code. (REG, as an example.) Thank you for considering my views.

Sincerely,

J & K Fresh, LLC

Lynnette Keffer
President

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